Exhibit L

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

020687Orig1s020

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration 10903 New Hampshire Avenue Building #51 Silver Spring, MD 20993

THRU: RE: NDA 020687, Supp 20 The currently approved REMS for Mifeprex contains a Patient Agreement Form required to be signed by both the patient and the prescriber. During the review of the REMS in connection with supplement 20 to NDA 020687 submitted by the sponsor. found that the information contained in the Patient Agreement Form is generally duplicative of information in the Medication Guide and of information and counseling provided to patients under standard informed consent practices for medical care and under professional practice guidelines. For the reasons further described in their reviews, the reviewers recommended that the Patient Agreement Form be removed from the REMS. After being briefed on the planned changes to the NDA that the Center was considering, the Commissioner concluded that continuing the REMS requirement for a signed Patient Agreement Form would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care. He requested that the Patient Agreement Form be retained as an element of the REMS.						
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to continue to include a Patient Agreement Form in the REMS for Mifeprex.	Therefore,		(b) (6) and de a Patient Agreem	ent Form in the RFMS		

Reference ID: 3909487

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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/s/

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03/29/2016 adding to for the record